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**UNITED STATES DISTRICT COURT  
 NORTHERN DISTRICT OF CALIFORNIA  
 SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA; STATES OF  
 CALIFORNIA, COLORADO, CONNECTICUT,  
 DELAWARE, FLORIDA, GEORGIA, HAWAII,  
 ILLINOIS, INDIANA, IOWA, LOUISIANA,  
 MICHIGAN, MINNESOTA, MONTANA,  
 NEVADA, NEW JERSEY, NEW MEXICO,  
 NEW YORK, NORTH CAROLINA,  
 OKLAHOMA, RHODE ISLAND,  
 TENNESSEE, TEXAS, VERMONT, AND  
 WASHINGTON; THE COMMONWEALTHS  
 OF MASSACHUSETTS AND VIRGINIA; AND  
 THE DISTRICT OF COLUMBIA,

*ex rel.* ZACHARY SILBERSHER,

Plaintiffs,

v.

ALLERGAN PLC, ALLERGAN, INC.,  
 ALLERGAN USA, INC., ALLERGAN SALES,  
 LLC, FOREST LABORATORIES HOLDINGS,  
 LTD., ADAMAS PHARMA, AND ADAMAS  
 PHARMACEUTICALS, INC.,

Defendants.

Case No.: 3:18-cv-03018-JCS

**PLAINTIFF-RELATOR ZACHARY  
 SILBERSHER'S OPPOSITION TO  
 ADAMAS DEFENDANTS' MOTION  
 TO DISMISS (DKT. 68)**

Hon. Joseph C. Spero

Courtroom G, 15th Floor  
 Phillip Burton Federal Building  
 450 Golden Gate Avenue  
 San Francisco, CA 94102

Hearing Date: October 25, 2019  
 at 9:30 a.m.(Dkt. 76)

Action Filed: April 25, 2018

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## INTRODUCTION

Adamas<sup>1</sup> in its motion to dismiss (Dkt. 68) (the “MTD”) repeats many of the same arguments that Allergan makes in its motion to dismiss (Dkt. 63). Those arguments lack merit for the reasons set forth in Relator’s brief in opposition to the motion to dismiss filed by Allergan (“Pl. Opp. to Allergan MTD”). (Dkt. 80) In this opposition brief, Relator focuses on addressing arguments that are either specific to Adamas or which were not raised in Allergan’s motion to dismiss.

As more fully set forth in Relator’s brief opposing Allergan’s motion, the First Amended Complaint (Dkt. 12) (“Complaint”) alleges that Defendants<sup>2</sup> fraudulently obtained patents to unlawfully extend their drug monopolies on Namenda XR and Namzaric. Those two drugs cost more than \$450 for a one-month prescription. Medicare and Medicaid paid over \$3.1 billion for them from 2014 through 2017 (the last date full data is available). Generic competition would have decreased Defendants’ market share by as much as 90% and brought market prices down by as much as 90%. Through their fraudulent scheme, Defendants unlawfully extended their patent monopoly and continued charging the government monopoly prices well after the initial patents for the drugs expired. Defendants reported those prices to the government as if they were fair and reasonable when Defendants knew they were unlawfully inflated through their fraudulent scheme. Defendants’ “fraudulent course of conduct” thus caused many government programs to pay too much for the drugs, violating the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733. *See U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017).

Defendants’ conduct gives rise to liability under three independent theories. First, Defendants committed a fraud on the Patent Office that tainted subsequent claims for payment, rendering them fraudulent under the FCA. As the Ninth Circuit has held in indistinguishable circumstances, this misconduct is actionable under the “promissory fraud” or “fraud in the inducement” doctrine. *See Campie*, 862 F.3d at 904 (holding that fraud on the Food and Drug Administration (“FDA”) during the

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<sup>1</sup> Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc.

<sup>2</sup> Allergan, Inc., Allergan USA, Inc., and Allergan Sales, LLC, and Forest Laboratories Holdings, Ltd. (collectively, “Allergan”); and Adamas Pharma and Adamas Pharmaceuticals, Inc. (together, “Adamas”) (“Allergan” and “Adamas” together, “Defendants”).

1 drug approval process gave rise to a promissory fraud claim vis-à-vis subsequent claims for payment  
 2 relating to the affected drugs); *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir.  
 3 2006) (holding that fraudulently obtaining agreement with the Department of Education gave rise to an  
 4 FCA claim with respect to downstream grants; and further holding that “the precise logistical details of  
 5 how the claim is made—with respect to timing, for instance, or the number of stages involved—are  
 6 immaterial” as long as the “false statement is integral to a causal chain leading to payment”).

7 Second, while negotiating the prices the government would pay for Namenda XR and  
 8 Namzaric, Defendants submitted pricing information to the government that a government purchaser  
 9 reasonably, but incorrectly, would have understood to reflect fair market conditions—while omitting  
 10 that the prices were in fact tainted by fraud. This is actionable under the FCA pursuant to the implied  
 11 certification doctrine. *See Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2000-  
 12 01 (2016); *Campie*, 862 F.3d at 901. These two theories of liability were fully explained Section III of  
 13 Relator’s opposition to Allergan’s motion to dismiss. (Dkt. 80, at pp. 15-20)

14 Third, the Complaint’s well-pleaded facts also establish that the patent applications themselves  
 15 constituted false claims, and the false statements made during patent prosecution were material to  
 16 those claims. 31 U.S.C. § 3729(a)(1)(A), (B). Adamas emphasizes in its opposition that, unlike  
 17 Allergan, it was not involved in the last step of the fraudulent scheme because it left Allergan to  
 18 submit claims to the government and list the drugs on the Federal Supply Schedule (“FSS”). (MTD, at  
 19 8) But as explained more fully below, a “claim” under the FCA includes any request for property—  
 20 and patents are property. Thus, Defendants’ patent applications were false claims, which proximately  
 21 caused the government to suffer significant damages. Adamas was clearly involved in those false  
 22 claims. None of Defendants’ arguments relating to materiality or Rule 9 refute liability with respect to  
 23 this basis for liability.<sup>3</sup>

24 Moreover, Adamas was directly involved not only in fraudulently procuring the Went Patents,  
 25 but also in asserting them against generic competitors that filed Abbreviated New Drug Applications

26 <sup>3</sup> This argument also applies to Allergan with respect to the false statements that its predecessor in  
 27 interest, Forest, made to the Patent Office.

1 (“ANDAs”) to introduce bioequivalent alternatives to Namenda XR and Namzaric. (Complaint, ¶¶ 58-  
 2 90; 104-09)<sup>4</sup> These acts—obtaining the patents and asserting them against generic competitors—were  
 3 key parts of the fraudulent scheme because they enabled the subsequent fraudulent claims for  
 4 payment. Thus, it makes no difference whether Adamas itself submitted the actual invoices or  
 5 presented the drugs for listing on the FSS. Adamas is jointly and severally liable with Allergan for  
 6 materially participating in, and benefiting from, the fraudulent scheme alleged in the Complaint.  
 7 Indeed, the FCA specifically prohibits misconduct that “causes” a “false or fraudulent claim” or  
 8 “statement material to a false or fraudulent claim” to be made or presented to the government—and  
 9 not just the actual submission of such claim or material statement. 31 U.S.C. §§ 3729(a)(1)(A), (B).

10 Adamas says that the Complaint should be dismissed under the FCA’s public disclosure bar, 31  
 11 U.S.C. § 3730(e)(4)(A). In addition to repeating Allergan’s arguments, Adamas adds that Defendants’  
 12 fraud was publicly disclosed by generic competitors that asserted inequitable conduct defenses to  
 13 patent infringement actions Defendants filed against them beginning in 2014. Adamas also says that  
 14 those pleadings were disclosed to the Patent Office in 2016 (without description, along with thousands  
 15 of other listed references) in subsequent patent applications not relevant to this suit. (MTD, at 7) This  
 16 argument fails because patent infringement actions are civil proceedings in which the government is  
 17 not a party. Congress specifically excluded information disclosed in such proceedings from the scope  
 18 of the public disclosure bar in 2010. 31 U.S.C. § 3730(e)(4)(A)(i). The fact that those pleadings were  
 19 later listed in a subsequent patent application does not help, because information disclosed in patent  
 20 prosecution proceedings are similarly excluded from the public disclosure bar under  
 21 § 3730(e)(4)(A)(i), as amended in 2010. That is because, like patent infringement actions, patent  
 22 prosecution proceedings (which are *ex parte*) are administrative proceedings in which the government  
 23 is not a party. *See, e.g., ICU Med., Inc. v. B. Braun Med. Inc.*, 2005 WL 588341, at \*13 (N.D. Cal.  
 24 Mar.14, 2005). Accepting Adamas’s argument would undermine Congress’s decision to exclude

25 \_\_\_\_\_  
 26 <sup>4</sup> The documents that Adamas asks the Court to take judicial notice confirm that Adamas  
 27 Pharmaceuticals, Inc. and Allergan’s predecessor in interest, Forest Laboratories, Inc. (with Forest  
 28 Laboratories, LLC, “Forest”), asserted the fraudulent patents to block generic competitors. *See, e.g.,*  
 Portelli Decl. Exs. 1-4.

1 information disclosed in such proceedings, in conflict with the statutory text, precedent, and  
 2 Congress’s policy objectives.

3 In any event, the mere listing of the pleadings filed in the infringement actions in a subsequent  
 4 and completely irrelevant patent application does not disclose anything material about the fraud  
 5 alleged in the Complaint. Indeed, the pleadings asserting inequitable conduct constituted two  
 6 references buried among thousands of citations summarily listed in two Information Disclosure  
 7 Statements filed by Adamas in the other patent applications—years after the last of the Went Patents  
 8 and the ’009 Patent had been granted.<sup>5</sup> None of the citations to the pleadings contain any description  
 9 or indication of their contents. Thus, even if the Information Disclosure Statements counted as “public  
 10 disclosures”—and they do not—such filings did not disclose anything material about the fraud alleged  
 11 in the Complaint.

12 Failing to come up with anything new that would merit dismissal of the Complaint, Adamas  
 13 resorts to the discredited canard that this suit is “parasitic.” Adamas says that “[p]arasitic lawsuits” are  
 14 “Mr. Silbersher’s business model.” (MTD, at 10) It is true that this case involves a parasitic business  
 15 model—but that description aptly describes Defendants’ scheme, and not Relator’s suit.<sup>6</sup> Relator has  
 16 brought a meritorious action—which alleges with specificity a fraudulent course of conduct that  
 17 Defendants do not deny on the merits—to recover billions of dollars that *Defendants* overcharged  
 18 government healthcare programs through their fraudulent scheme. There is no reason to believe  
 19 anybody in the government was aware of this fraud, much less that the massive overcharges would  
 20 ever have been recovered if Relator had not diligently uncovered it and filed this action. A parasite  
 21 feeds on a host; and here, Defendants are the ones unlawfully enriching themselves with government  
 22 healthcare funds, and Mr. Silbersher is trying to stop it and recover the billions that Defendants  
 23 wasted.

24  
 25 <sup>5</sup> See Declaration of Anthony L. Portelli dated June 21, 2019, Exs. 5 & 6. (Dkt. 69)

26 <sup>6</sup> Indeed, Allergan helpfully points out that the New York Attorney General and several antitrust  
 27 plaintiffs previously sued Defendants for unlawfully excluding generic competitors from introducing  
 28 lower-priced generic drugs in connection with Namenda IR, the previous version of Namenda XR. *See*  
 Pl. Opp. to Allergan MTD, Dkt. 80, at pp. 22-23; *see also* Allergan’s MTD, Dkt. 63, at p. 14.

## BACKGROUND

The relevant facts and background are fully set forth Relator's opposition brief to Allergan's motion to dismiss, and Relator incorporates them here. (Dkt. 80, at pp. 4-7) The relevant facts as they pertain to the additional arguments raised in Adamas's motion are set forth below.

Adamas is the original owner of the Went Patents, which are named after Dr. Gregory T. Went, the founder and CEO of Adamas. (Complaint, ¶ 58) Adamas entered into a commercialization and development agreement with Allergan's predecessor in interest, Forest, and granted Forest an exclusive license with respect to all of the Went Patents in November 2012. (Complaint, ¶ 58) Together, Adamas and Allergan developed and commercialized Namenda XR and Namzaric. (Complaint, ¶¶ 49, 53) Adamas also conducted the clinical study known as ME110 (the "ME110 Study"). The Complaint alleges that the Went Patents were fraudulently obtained through Dr. Went's misrepresentations concerning the results of the ME110 Study, which was the basis upon which Defendants tricked the Patent Office into issuing the Went Patents. (Complaint, ¶¶ 63-90)

The Complaint alleges that Defendants used their fraudulently obtained patents to block generic competition for Namenda XR and Namzaric. It alleges that sixteen generic manufacturers had filed ANDAs and were prepared to generic alternatives to Namenda XR by the end of December 2013, and to Namzaric by July 13, 2015. (*Id.*, at ¶¶ 104-05 & 108-09) However, Defendants delayed generic entry by listing their patents in the Orange Book and initiating infringement actions asserting the Went Patents and the '009 Patent against generic competitors. (*Id.*, at ¶¶ 104-109; *see also* n.4, *supra*)

This fraud harmed the government in two ways. First, government health programs frequently favor less expensive generic drugs. (*Id.*, ¶ 121-23, 130) By unlawfully excluding generic competitors from the market altogether, Defendants denied the government that choice and significant cost savings. Second, the prices the government pays for drugs are based on market prices. Indeed, the government is prohibited from paying more than a percentage (76%) of the average manufacturer's price for the drugs under Medicaid and certain other government programs, such as the Veterans' Health Administration. (*Id.*, at ¶¶ 112-16) Thus, when a drug manufacturer unlawfully manipulates the market price, it necessarily also manipulates the price the government will pay.

## ARGUMENT

As the Ninth Circuit has repeatedly confirmed, the FCA is “intended to reach all types of fraud, without qualification, that might result in financial loss to the Government.” *Hendow*, 461 F.3d at 1170–71; *see also Campie*, 862 F.3d at 899 (“We construe the Act broadly”). To allege an FCA claim, Relator must plead: “(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.” *Campie*, 862 F.3d at 899. As explained in the Introduction, and as established by the allegations in the Complaint and summarized in the Background section, this case falls squarely within the heartland of the FCA: Defendants committed fraud to cause the government to pay more for medicines.

The Complaint alleges that Defendants did three fraudulent things, each of which tainted claims for payment made to the government: (1) Defendants got their patents through fraud on the Patent Office; (2) Defendants knowingly used these invalid patents to block or delay generic competition, inflating the market price and securing their market share through fraud (and thus denying government payors choice in the marketplace); and (3) Defendants provided tainted and misleading pricing information to government payors, leading to contracts that caused the government to pay Defendants more than it otherwise would have. This conduct gives rise to liability under the theories of promissory fraud (whereby upstream fraud on the patent office tainted downstream claims for payment), implied false certification (for misleading the government into believing that the prices offered to the market were not tainted by fraud), and factually false claims (the patent applications themselves, which were obtained through misrepresentations and misleading omissions). Each of these theories renders Adamas liable for the government’s damages and civil monetary penalties.

### **I. Adamas Played an Important Role in Fraudulently Procuring and Asserting the Went Patents**

Adamas does not dispute the Went Patents were obtained by fraud because Dr. Went—Adamas’s founder and CEO—lied about the results of the ME110 Study, and his lies caused the Patent Office to issue the Went Patents. Instead, Adamas argues that the Complaint is supposedly devoid of any facts suggesting Adamas provided inaccurate or misleading pricing information to the government

1 in connection with drug pricing. (MTD, at 3 & 8) Instead, it points the finger at Allergan, which was  
 2 responsible for marketing Namenda XR and Namzaric.

3 Adamas's argument ignores the statutory text, which applies not only to any person who  
 4 submits a false claim, but also to any person who "causes" such a claim to be submitted. *See* 31 U.S.C.  
 5 § 3729(a)(1)(A), (B). Defendants' fraudulent scheme included obtaining the patents, and then  
 6 wrongfully asserting those patents against generic competitors to force the government to buy from  
 7 Defendants at inflated prices. Adamas played key roles in these critical parts of the fraud. Through its  
 8 misconduct, Adamas "caused" the submission of false claims to the government. *See Campie*, 862  
 9 F.3d 890, 903 (holding that as long as a defendant's false statements are an essential part of a causal  
 10 chain leading to payment, the defendant is liable under the FCA); *see also, e.g., Mortgs., Inc. v. United*  
 11 *States Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991) ("Where one or more persons have committed a  
 12 fraud upon the government in violation of the FCA, each is joint and severally liable for the treble  
 13 damages and statutory penalty."). Adamas cannot evade culpability simply by claiming it was not  
 14 active in the last step in the causal chain (although Adamas benefited from it). And its reliance on  
 15 *Hascoet ex rel. U.S. v. Morpho S.A.*, No. 17-16915, 2019 WL 2213322 (9th Cir. May 22, 2019) is  
 16 inapposite, because the Complaint here pleads with specificity Adamas's critical involvement in the  
 17 fraudulent scheme.

18 Moreover, Dr. Went's fraud on the Patent Office—which Adamas's motion does not contest—  
 19 is chargeable to all those who acquire or enforce the patents. *See In re Rembrandt Techs. LP Patent*  
 20 *Litig.*, 899 F.3d 1254, 1272 (Fed. Cir. 2018) (affirming imposition of sanctions on purchaser of a  
 21 patent based on prior owner's inequitable conduct); *Avid Identification Sys., Inc. v. Crystal Import*  
 22 *Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("If an individual who is substantively involved in the  
 23 preparation or prosecution of an application fails to comply with his duty of candor, then that  
 24 individual's misconduct is chargeable to the applicant for the patent, and the applicant's patent is held  
 25 unenforceable."). It is surely chargeable to Adamas, because Dr. Went was its CEO and founder, and  
 26 the patents were assigned to Adamas in the first instance. *Cf. United States ex rel. Polukoff v. St.*  
 27 *Mark's Hosp.*, 895 F.3d 730, 745 n.9 (10th Cir. 2018), *cert. dismissed* 2019 WL 188163 (U.S. June 10,

2019) (holding that FCA liability for a corporation can be established if any of its agents or employees acting within the scope of their authority knew of the fraud).

## **II. The Complaint Pleads False Claims and Statements**

Adamas focuses its argument on its mistaken belief that Relator solely “relies on the implied certification doctrine in an unsuccessful attempt to satisfy the FCA’s falsity element.” (MTD, at 2) While that is one theory upon which FCA liability is based, Adamas misses the Complaint’s well-pleaded allegations supporting liability based on promissory fraud (*i.e.*, Defendants’ upstream fraud on the Patent Office tainted all downstream claims for payment); and express fraud (*i.e.*, the fraudulent patent filings directly give rise to FCA liability as false “requests” for “property”).

### **A. Promissory Fraud or Fraud in the Inducement**

The FCA is broadly construed to apply to situations like here in which an upstream fraud is used to facilitate downstream claims. *See Campie*, 862 F.3d at 903; *Hendow*, 461 F.3d at 1174; *see also U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 539 & n.1, 542-44 (1943); *see generally*, Pl. Opp. to Allergan’s MTD, Dkt. 80, at pp. 2, 8, 15, 18. Adamas’s arguments do not address liability on this basis, and Defendants fail to draw the necessary distinction between this basis for liability and implied certification. This is fatal to their defenses.

Although there is some overlap between fraud in the inducement and implied false certification, the two theories address distinct misconduct. Fraud in the inducement occurs when a defendant fraudulently induces the government to confer a benefit on the defendant that taints subsequent claims for payment. The best example in this Circuit is the court of appeals’ decision in *Campie*. There, the relator alleged, among other things, that the defendant fabricated test results in order to deceive the FDA into approving the use of active pharmaceutical ingredients from a facility in China. The district court had dismissed the claim because the alleged misrepresentations were not made to the paying agencies that bought the drugs (the same paying agencies at issue here), deeming the relationship between the misrepresentations and the claims for payment too attenuated to support liability. The Ninth Circuit reversed, explaining that “the False Claims Act imposes no such limitation” that false claims only arise when misrepresentations are made to paying agencies. 862 F.3d

1 at 903. The court of appeals explained that “[i]t is not the distinction between the agencies that  
2 matters, but rather the connection between the regulatory omissions and the claim for payment.” *Ibid.*  
3 When “a false statement is integral to a causal chain leading to payment, it is irrelevant how the  
4 federal bureaucracy has apportioned the statements among layers of paperwork.” *Ibid* (quoting  
5 *Hendow*, 461 F.3d at 1174).

6 The misstatements to the FDA in *Campie* established an FCA claim based on the doctrine of  
7 promissory fraud (or fraud in the inducement), which holds that “subsequent claims are false because  
8 of an original fraud.” 862 F.3d at 902. The defendant’s misrepresentations to the FDA in *Campie*  
9 enabled the defendant to seek government payments for the drugs. *Id.* at 904. Those  
10 misrepresentations meant that “each claim was fraudulent even if false representations were not made  
11 therein.” *Ibid.* In other words, the upstream fraud tainted the downstream claims.

12 *Campie* controls here. Defendants were only able to submit the extremely lucrative claims for  
13 payment that they later submitted—*i.e.*, to charge the prices they charged, and to monopolize the sale  
14 of these drugs—because they first defrauded the Patent Office. That fraud, like the fraud on the FDA  
15 in *Campie*, was integral to the causal chain leading to the claims for payment, and it therefore taints  
16 those claims.

17 Similarly, in *United States v. DynCorp Int’l, LLC*, 253 F. Supp. 3d 89 (D.D.C. 2017), the  
18 defendant told the government during contract negotiations that it would charge labor rates based on  
19 “historical data.” *Id.* at 106. Without telling the government, the defendant also charged its overhead  
20 and profit on top of inflated labor rates. *Ibid.* The court held that this conduct was actionable  
21 promissory fraud because, by omitting material information concerning its rates, the defendant skewed  
22 the initial price negotiations with the government and caused it to agree to pay higher prices in  
23 subsequent claims than what the government otherwise would have paid. *Id.* at 107-08. Again, the  
24 upstream or original fraud resulted in price inflation that were incorporated in downstream or  
25 subsequent claims, and the FCA provided a remedy. The same principle applies to this case as well.

## B. Implied Certification

Adamas argues that the implied certification doctrine does not apply because, according to Adamas, the GSA is indifferent about whether the prices the government pays are actually “fair and reasonable.” (MTD, at 18-19) All the GSA wants to know, says Adamas, is whether the government is paying the same prices as commercial payors. So long as a seller accurately reports the prices that it charges to commercial payors, it has satisfied all of its regulatory obligations—even if that price is tainted by fraud.

On its face, that argument is implausible because *no reasonable payor* would be indifferent about whether it was paying a price for drugs that had been inflated 650% due to fraud. (*See* Complaint ¶¶ 155). The GSA seeks information about what commercial payors are paying because it reasonably assumes commercial payors are paying fair market value. But when, as here, a defendant knows that it has distorted the market price through a fraudulently obtained patent monopoly, the defendant knows that the government’s reasonable assumption is false. In this context, blithely reporting the prices that commercial payors pay—without disclosing that the prices have been unlawfully inflated—is precisely the same sort of misleading half-truth the Supreme Court found actionable in *Escobar*. There, the defendant submitted claims for reimbursement using billing codes corresponding to the provision of counseling services, such as “Family Therapy” by “Social Workers, Clinical.” *See* 136 S. Ct. at 1997 & 2000. The Court held that the claims were actionable because the use of the billing codes was “clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that” the social worker was qualified and licensed under Massachusetts law. *Id.* at 2000. The social worker was not licensed in Massachusetts, and therefore the use of the billing codes “without disclosing [the defendant’s] many violations of basic staff and licensing requirements . . . constituted misrepresentations” actionable under the FCA. *Id.* at 2000-01. In so holding, the Supreme Court stressed that courts should not “adopt a circumscribed view of what it means for a claim to be false or fraudulent.” *Id.* at 2002 (quotation marks omitted).

Under *Escobar*, Defendants’ statements to the GSA are actionable here. Anybody receiving Defendants’ reported “lowest price charged to any commercial customer” would probably—but wrongly—conclude that such price reflected fair market conditions. This is especially true because the government’s specific instructions made absolutely clear that Defendants’ reported price would serve as the basis for ensuring that the price the government was charged for the medicines remained “fair and reasonable throughout the life of the contract.” (Complaint, ¶ 112) Defendants’ statements, like the statements in *Escobar*, were clearly misleading in context. This also answers Adamas’s argument that to state an implied certification claim, the claim must make a specific representation about the goods and services provided, while failing to disclose material noncompliance with a regulatory requirement that renders the specific representations misleading. In this case, Defendants specifically provided the government the best commercial prices charged for Namenda XR and Namzaric to ensure the government paid “fair and reasonable” prices for them, without disclosing that the reported prices were inflated tenfold by Defendants’ fraudulently obtained patent monopoly.

### **C. The Fraudulent Patent Applications Are Also False Claims**

The discussion so far has focused on the claims for payment submitted to government health care programs. As explained above, Adamas is jointly and severally liable for these claims, regardless of whether Adamas directly submitted claims to the government. Additionally, the facts alleged in the Complaint support Adamas’s liability for expressly false misrepresentations because the fraudulent patent applications themselves constituted false claims.

While most FCA claims are predicated on claims for payment of money, the statute sweeps far more broadly. Thus, a “claim” is defined as “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—(i) is presented to an officer, employee, or agent of the United States.” 31 U.S.C. § 3729(b)(2)(A). Under this plain language, an application for a patent fits the definition of a claim because it is a “request” for “property” that is “presented to an officer, employee, or agent of the United States.” The only remaining question is whether a patent constitutes “property” under the FCA.

Patents are traditionally described as “intellectual property,” because by their terms, patents “claim” inventions from the public domain for the exclusive benefit of the patentee. As the Supreme Court has explained, patents create a property right in the form of a public franchise. *See Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1373-75 (2018).<sup>7</sup> Indeed, the Patent Act expressly provides that “[s]ubject to the provisions of this title, patents shall have the attributes of personal property.” 35 U.S.C. § 261. Thus, patent owners have the traditional powers associated with property rights, including, most importantly, the power to exclude others from practicing their inventions.

Adamas’s fraudulent patent application therefore constitutes an independent violation of the FCA, and it is irrelevant that Adamas did not directly submit any claims to the government.<sup>8</sup> This

<sup>7</sup> The Supreme Court has confirmed, time and again, that patents are property. *See, e.g., Mission Prod. Holdings, Inc. v. Tempnology, LLC*, 139 S. Ct. 1652, 1659 (2019); *Horne v. Dep’t of Agric.*, 135 S. Ct. 2419, 2427 (2015); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002). Indeed, the Court’s precedents to this effect go back over a century. *See, e.g., Brown v. Duchesne*, 19 How. 183, 197 (1857).

<sup>8</sup> We anticipate that Adamas may cite *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1380 (Fed. Cir. 2000), *amended* (Apr. 5, 2000). There, the Federal Circuit held that inequitable conduct on the Patent Office could not establish the predicate offenses of mail fraud and wire fraud for a RICO claim. The court determined that in the context of those statutes, a claim for fraud required the defendant to deprive the victim of property the victim possessed, but an unissued patent is not property in the government’s hands. *See ibid.* The court also rejected the claimant’s “attempt to analogize a patent to a franchise,” which would have supported a fraud claim because circuit courts had held the fraud statutes apply to fraudulent attempts to obtain a franchise. *Ibid.*

For two reasons, *Semiconductor Energy Laboratory* does not control here and is not persuasive. First, the mail and wire fraud statutes are different from the FCA. Those laws have long been interpreted narrowly to apply only to schemes to take property in the victim’s hands, and Congress has acquiesced in that interpretation. *See McNally v. United States*, 483 U.S. 350, 360 (1987) (mail fraud statute was intended “to protect the people from schemes to deprive them of their money or property”); *Cleveland v. United States*, 531 U.S. 12, 19-20 (2000) (reviewing amendment history of the mail fraud statute to conclude that Congress had intended to codify this understanding). In contrast with the mail and wire fraud statutes, controlling precedent holds that the FCA should be construed “broadly” to achieve its remedial purpose. *Campie*, 862 F.3d at 899. That is especially the case here because Congress deliberately broadened the FCA in 2009 by adding the phrase “whether or not the United States has title to the money or property” to the definition of a “claim,” making it clear that fraud under the FCA is not limited to attempts to obtain property in the government’s hands. 31 U.S.C. § 3729(b)(2)(A). As the Supreme Court has recognized, such broadening signals Congress’s intent to depart from the narrow understanding of fraud embodied in the mail and wire fraud statutes. *See Loughrin v. United States*, 573 U.S. 351, 360 (2014) (contrasting the mail fraud statute with the bank fraud statute, which Congress had expanded, and refusing to interpret the bank fraud narrowly in a manner that would “deprive that [expansion] of its full effect”). [continued on following page]

theory of FCA liability applies with equal force to Forest's conduct before the Patent Office, now attributable to Allergan as Forest's successor-in-interest.

### III. The Complaint Pleads Materiality

Adamas repeats the same arguments raised by Allergan with respect to materiality. For the reasons set forth in Relator's opposition to Allergan's motion to dismiss, the Court should reject those arguments as well. *See* Pl. Opp. to Allergan's MTD, at Section IV, pp. 20-21.

Adamas also argues that the government declined to intervene in this case or take action to halt the payments for Namenda XR and Namzaric. According to Adamas, this must mean that the fraud was not material. (MTD, at 21) Adamas's argument is based on a faulty factual premise: the government does not yet *know* there was fraud. Relator will prove that at trial. Moreover, there is no reason to presume that a decision by the government not to assume control of the suit is a commentary on the suit's merits: "The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney." *U.S. ex rel. Chandler v. Cook Cty., Ill.*, 277 F.3d 969, 974 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003). Assuming the government looked unfavorably upon each *qui tam* action in which it did not intervene would be "antithetical to the purpose of the *qui tam* provision—to encourage private parties to litigate on behalf of the government." *U.S. ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008). Not surprisingly, when defendants seek to introduce the government's declination at trial, courts exclude it as irrelevant. *See, e.g., U.S. ex rel. Feldman v. van Gorp*, No. 03 CIV. 8135 (WHP), 2010 WL 2911606, at \*2 (S.D.N.Y. July 8, 2010). The Court should therefore reject Adamas's unfounded suggestion that a government declination had anything to do with materiality.

Because it is at least plausible that Defendants' fraud—which the Complaint alleges had a massive effect on the price the government paid for these drugs—was material to the government's payment decisions, the motion to dismiss should be denied on this ground.

Second, the Supreme Court has subsequently rejected the essential holding of *Semiconductor Energy* that a patent is not a franchise. *See Oil States*, 138 S. Ct. at 1373 (holding that a patent is "a specific form of property right—a public franchise"). The Federal Circuit has acknowledged that fraudulently obtaining a franchise would be actionable. *See Semiconductor Energy*, 204 F.3d at 1380.

#### IV. The Complaint Pleads Scienter

Adamas suggests that because the Complaint alleges Dr. Went actively corrected past statements to the Patent Office “on multiple occasions,” the Complaint fails to plead scienter. (MTD, at 22) Relator, however, is only required to plead scienter “generally.” Fed. R. Civ. P. 9(b). *See also U.S. ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, No. CV 17-1694 PSG (SSX), 2019 WL 3282619, at \*22 (C.D. Cal. July 16, 2019) (holding that the complaint sufficiently alleged Defendants were seeking to increase Medicare revenue and were reckless). At best, Adamas’s argument raises an issue of fact—implausibly. The Complaint alleges that Adamas’s founder and CEO knew that he was intentionally misrepresenting the critical results of the ME110 Study, because he demonstrated knowledge of the actual results he failed to disclose. (*See, e.g.*, Complaint, ¶ 83) The Complaint also alleges that the CEO revised his original false declaration, but *not with respect to the critical misrepresentation* concerning the actual results of the ME110 Study, which he personally knew about. (Complaint, ¶¶ 80-83) This demonstrates that Adamas persisted in misleading the Patent Office on the most important facts that would have blocked the issuance of the Went Patents.

In any event, *Integra* demonstrates that the well-pleaded allegations in the Complaint easily satisfy any pleading requirements for scienter. Like the allegations in *Integra*, the Complaint’s “allegations taken together are enough to give rise to a plausible inference that Defendants were primarily focused on increasing their Medicare revenue such that they at least recklessly disregarded” the obvious invalidity of the Went Patents in light of Dr. Went’s knowledge of the true results of the ME110 Study, which were the exact opposite of what Adamas told the Patent Office on at least 10 separate occasions. *Integra*, 2019 WL 3282619, at \*22; *see also, e.g.*, Complaint, ¶¶ 83-90; 130, 149, 152-55.

#### V. The Complaint Satisfies Rule 9(b)

Peppered throughout its brief, Adamas makes fleeting references to Rule 9(b). The Court should ignore them. Under Rule 9(b), “it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010). That is because, as

the court recognized in *U.S. ex rel. Integra Med Analytics LLC v. Providence Health & Servs*, No. CV 17-1694 PSG (SSX), 2019 WL 3282619, at \*21 (C.D. Cal. July 16, 2019), the purpose of Rule 9 is to provide defendants with “sufficient notice of the allegedly fraudulent conduct.”

Like the allegations in *Integra*, the Complaint easily satisfies Rule 9. The Complaint adequately alleges the “who, what, when where, and how” of the fraud. *Id.* With respect to the fraud on the Patent Office relating to the Went Patents, the “who” is Dr. Went and the patent attorneys who submitted the misleading declarations on behalf of Adamas and Allergan (Complaint, ¶¶ 58-90). The “what” is the fraudulent submission of test results to the Patent Office that was critical in misleading the Patent Office to grant the Went Patents (*Id.*). The “when” is, *inter alia*, the specific dates between November 5, 2010 through the submission of the ‘233 Patent application (filed on January 28, 2013) (*See, e.g.*, Complaint, ¶¶ 61-63, 69, 71, 73-77, 80-82 ). The “where” is the Patent Office (*See, e.g.*, Complaint, ¶ 61). The “how” is Defendants’ misstating the actual results of the ME110 Study to imply that the extended release formulation of Namenda XR had lower incidents of central nervous system side-effects than the immediate release version, when the exact opposite was true (*See, e.g.*, Complaint ¶¶ 59-63, 67-69, 74-83). Similarly, the Complaint pleads sufficient detail to put Defendants on sufficient notice with respect to the fraud relating to the ‘009 Patent (Complaint, ¶¶ 91-102); and the listing of the drugs on the Federal Supply Schedule (Complaint, ¶¶ 111-18).<sup>9</sup> The Complaint also alleges reliable “indicia” that false claims were submitted, detailing hundreds of thousands of false claims for Medicare and Medicaid. (*See e.g.*, Complaint, ¶¶ 124-27, 132, 136)

By comparison, the Complaint is much more detailed than the allegations that the *Integra* court found sufficient. The *Integra* court held that even though the allegations in the complaint did not identify the precise individuals submitting false statements, the complaint nevertheless had sufficient detail to permit Defendants to “easily determine[]” who they were, and “therefore [such detail] did not need to be alleged in the complaint.” 2019 WL 3282619, at \*21. This is consistent with the Ninth Circuit’s rule that when the identities of specific persons are within Defendants’ knowledge, a relaxed

<sup>9</sup> The FSS schedule confirming the listing for Namenda XR Namzaric, and providing specific detail concerning, *inter alia*, the vendor responsible for the listing (Allergan), the date, and the price, can be accessed and downloaded in Excel format at: <https://www.va.gov/opal/nac/fss/pharmPrices.asp>.

Rule 9(b) pleading standard is applied to the allegations in the Complaint. *Breville Pty Ltd. v. Storebound LLC*, No. 12-CV-01783-JST, 2013 WL 1758742, at \*5 (N.D. Cal. Apr. 24, 2013) (analyzing inequitable conduct allegations, which are more stringent than what is required for FCA claims).

#### **VI. Adamas's Public Disclosure Argument Lacks Merit**

Adamas repeats the same arguments raised by Allergan with respect to the public disclosure bar. For the reasons set forth in Relator's opposition to Allergan's motion to dismiss, the Court should reject those arguments as well. *See* Pl. Opp. to Allergan's MTD, Section V, at pp. 21-28).

Adamas, like Allergan, relies heavily on the patent prosecution dockets to argue that their false submissions to the Patent Office were publicly disclosed under the FCA. But Defendants cannot rely on their own fraudulent patent submissions to support an argument that public disclosure has occurred. *Cf. U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 183 (E.D. Pa. 2012) ("To now accept Defendants' theory would mean that by their very act of submitting their allegedly false claim via the PDE reports, Defendants have effectively shielded themselves from FCA liability through the public disclosure bar. This clearly cannot be the correct result.")

Adamas tries to add to Allergan's argument by saying that certain generic ANDA filers asserted inequitable conduct as affirmative defenses in actions beginning July 2014 through 2016. (MTD, at 5-7) This changes nothing, because those inequitable conduct allegations were pleaded in connection with patent infringement actions, which are civil actions in which the government is not a party. Congress specifically amended the FCA in 2010 to exclude such information from the public disclosure bar. 31 U.S.C. § 3730(e)(4)(A)(i). Adamas, like Allergan, also tries to rely on *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 705 (9th Cir. 2017). But like Allergan, Adamas completely misses that *Amphastar's* public disclosure holding was superseded by Congress in 2010, and that if anything, the district court's decision in *Amphastar* confirms the viability of Relator's claims. *See generally* Pl. Opp. to Allergan's MTD, at pp. 18, 19 & 25); *see also Amphastar*, 2013 WL 12139832, at \*3 and 2012 WL 5512466, at \*9-13.

Nor can Adamas circumvent Congress's amendments by claiming that because the dockets in the infringement actions were available on PACER, such information was disclosed as a "Federal

report” or “news media” under §§ 3730(e)(4)(A)(ii), (iii). *See* Pl. Opp. to Allergan’s MTD, Section V(B), at pp. 23-28 (explaining that the specific provisions in §3730(e)(4)(A)(i) governs the more general provisions in §§ 3730(e)(4)(A)(ii), (iii); that such an approach would be inconsistent with controlling precedent; that such an approach is inconsistent with those terms’ ordinary meaning; that doing so would be contrary to the policies behind the public disclosure provision; and that the well-reasoned decision in *Integra*, 2019 WL 3282619, at \*11, rejects the notion that information available in PACER can possibly support a public disclosure bar in light of the 2010 amendments to the FCA).

Adamas also tries to argue that the information in the patent infringement pleadings was disclosed by Adamas in documents attached to Information Disclosure Statements submitted to the Patent Office in connection with different, wholly irrelevant patent applications filed in April 2016. (MTD, at 2 & 7; Portelli Decl., Exs. 5 & 6) But these disclosures do not fall within any enumerated public forum in the FCA. *See* Pl. Opp. to Allergan’s MTD, at Section V, pp. 23-28.

Adamas argues that the patent prosecution docket constitutes a federal report, citing a snippet of a footnote of dictum from an out-of-circuit decision concluding that SEC filings constitute public disclosures. (MTD, at 13, *citing U.S. ex rel. Ryan v. Endo Pharmaceuticals, Inc.*, 27 F. Supp. 3d 615 (E.D. Pa. 2014)) That decision is, to say the least, unpersuasive: The court stated that a 10–k filing with the SEC qualifies as a federal report. This was a single sentence in a footnote, without any analysis, after the court already found that those relators’ complaints were barred by the first-to-file rule. *Id.* at 628, & n.16. Moreover, the court’s statement concerning SEC filings is at odds with decisions that require a “Federal report” to have at least been an actual *report* prepared by a government representative who gathered what the representative determined to be relevant information responsive to a specific inquiry, such as a FOIA request in *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401 (2011); or a request to CMS for certain Medicare data in *Integra*, 2019 WL 3282619, at \*6. For the reasons set forth in Relator’s brief in opposition to Allergan’s motion to dismiss, the Court should adhere to the ordinary meaning of “Federal report” in § 3730(e)(4)(A)(ii) and reject Adamas’s suggestion to extend *Ryan* to patent prosecution filings. *See* Pl. Opp. to Allergan’s MTD, at Section V(B); *cf. State ex rel. Bartlett v. Miller*, 243 Cal. App. 4th 1398, 1410,

1 197 Cal. Rptr. 3d 673, 681 (2016) (an SEC filing is neither a “report” nor “news media” under  
2 California’s similar false claims statute).

3 Allergan cannot not cite a single case—controlling or otherwise—holding that documents  
4 available on the Patent Office’s PAIR online docket triggered the public disclosure bar under the current  
5 version of the statute. Similarly, Adamas cannot cite a single case that the PACER online docketing system  
6 can trigger a public disclosure bar either. To the contrary, the only court that appears to have analyzed this  
7 issue is *Integra*, and in a well-reasoned decision, the court rejected that argument. *Integra*, 2019 WL  
8 3282619, at \*11-12 (“Under Defendants’ view, the mere posting of the transcript on PACER or a tweet . . .  
9 could render the information from the hearing publicly disclosed under the FCA, even though it otherwise  
10 would not be. This would run contrary to the purposes underlying the public disclosure bar, and indeed the  
11 FCA itself”).

12 In any event, the April 2016 submissions do not actually disclose anything material about the  
13 fraud alleged in the Complaint. Rather, they merely list the generic ANDA filers’ pleadings—without  
14 any description whatsoever—along with thousands of other references also missing any meaningful  
15 descriptions. That is not the sort of specific disclosure of material allegations of fraud that the Ninth  
16 Circuit has required to invoke the public disclosure bar. *See U.S. ex rel. Mateski v. Raytheon Co.*, 816  
17 F.3d 565, 579 (9th Cir. 2016) (disclosed fraud was not substantially similar to the relator’s claim  
18 because “the prior reports could not have alerted the Government to the specific areas of fraud alleged  
19 by” the relator).

## 20 CONCLUSION

21 For the foregoing reasons, the Motion to Dismiss should be denied in its entirety. In the  
22 alternative, the Court should permit Relator to amend his pleadings should there be any deficiency.  
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Respectfully submitted,

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